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### **PATENT**

# In the UNITED STATES PATENT and TRADEMARK OFFICE

ALEWAPPLICANT:

Auestad, et al

SERIAL NO.:

10/625,420

FILED:

July 23, 2003

TITLE:

APPETITE CONTROL FORMULA

EXAMINER: Not yet assigned Not yet assigned ART UNIT: DOCKET NO.: 6960.US.P1

I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA, on the

date shown below.

Wendy Detwiler

Date

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL LETTER

Enclosed herewith is a Information Disclosure Statement and Form 1449 for the above-referenced patent application. Also enclosed is:

One (1) return postcard

If any fees are owed, or any credit is due pertaining to this case; please charge that fee or apply that credit to Deposit Account No. 01-0025.

Respectfully submitted,

Ross Products Division of ABBOTT LABORATORIES Department 108140/DS1 625 Cleveland Avenue Columbus, OHIO 43215-1724

Facsimile:

Telephone: 614/624-5686 614/624-3074

Docket: 6960.US.P1

William J. Winter Reg. No. 36,060



In the UNITED STATES PATENT and TRADEMARK OFFICE

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wendy Detrible 10-8-03
Wendy Detriller Date

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

#### Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- ☐ A copy of each cited reference is provided;
- Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard	l to pa	yment of a fee:
	×	No fee is due because:
۵	X	This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
		Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
		This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of \$180.00 is specified by 37 C.F.R. §1.17(p).

If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025.

Ross Products Division of ABBOTT LABORATORIES Dept. 108140-DS/1 625 Cleveland Avenue Columbus, OHIO 43215-1724

Telephone: (614) 624-5686 Facsimile: (614) 624-3074

Docket: 6960.US.P1

Respectfully submitted,

by William J. Winter Reg. No. 36,060

of <u>6</u> Sheet \_1 Atty. Docket No. 6960.US.P1 Serial No. U.S. Department of Commerce FORM PTO-1449 10/625,420 Patent and Trademark Office (Rev. 2032) Applicant INFORMATION DISCLOSURE STATEMENT BY APPLICANT Auestad, et al. Group

(Use several sheets if necessary)

Filing Date July 23, 2003

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Sheet 2 of 6

FORM PTO-1449 U.S. Department of Commerce 6960.US.P1 10/625,420

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Auestad, et al.

(Use several sheets if necessary)

Atty. Docket No. 6960.US.P1 10/625,420

Applicant Auestad, et al.

Filing Date Group

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Sheet 3 Serial No. Atty, Docket No. **U.S. Department of Commerce FORM PTO-1449** 6960.US.P1 10/645,420 **Patent and Trademark Office** (Rev. 2032) INFORMATION DISCLOSURE Applicant STATEMENT BY APPLICANT Auestad, et al. Filing Date Group (Use several sheets if necessary)

July 23, 2003 U.S. PATENT DOCUMENTS Filing Date (if appro.) Name Class Subclass Date Examiner Document Number Initial FOREIGN PATENT DOCUMENTS Class Subclass Translation (Yes No) Name Document Number OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Fride E, Ginzburg Y, Breuer A, Bisogno T, Di Marzo V, Mechoulam R. Critical role of the endogenous cannabinoid system in mouse pup suckling and growth. European Journal of Pharmacology, 419:207-214, (2001). Gaoni Y and Mechoulam R. Isolation, structure and partial synthesis of an active constituent of hashish. J. Am. Chem. Soc. 86:1646 (1964). Giang DK and Cravatt BF. Molecular characterization of human and mouse fatty acid amide hydrolases. Proc. Natl. Acad. Sci., 94:2238-2242, (1997). Giuffrida A, Beltramo M, and Piomelli D. Mechanisms of endocannabinoid inactivation: biochemistry and pharmacology. Journal of Pharmacology and Experimental Therapeutics, 298(1): 7-14, (2001). Goparaju SK, Ueda N, Yamaguchi H, and Yamamoto S. Anandamide amidohydrolase reacting with 2-arachidonovlglycerol, another cannabinoid receptor ligand. FEBS Letters. 422:69-73, (1998). Guzman M and Sanchez C. Effects of cannabinoids on energy metabolism. Life Sciences, 65 (6/7):657-664, (1999). Hanus L, Gopher A, Almog S, and Mechoulam R. Two new unsaturated fatty acid ethanolamides in brain that bind to the cannabinoid receptor. J Med. Chem., 36:3032-3034, (1993). Hao S, Avraham Y, Mechoulam, and Berry EM. Low dose anandamide affects food intake, cognitive function, neurotransmitter and corticosterone levels in diet-restricted mice. European Journal of Pharmacology, 392:147-156, (2000). Harnack LJ, Jeffrey RW, and Boutelle KN. Temporal trends in energy intake in the United States: an ecological perspective. An J Clin Nutr, 71:1478-1484, (2000). Havel PJ. Peripheral signals conveying metabolic information to the brain: short-term and long-term regulation of food intake and energy homeostatis. Exp Bio Med, 226 (11): 963-977. (2001). Heird WC. Parental feeding behavior and children's fat mass. Am J Clin Nutr, 75:451-452, (2002). Hillard CJ. Biochemistry and pharmacology of the endocannabinoids arachidonylethanolamide and 2-arachidonylglycerol. Prostaglandins and other Lipid Mediators, 61:3-18, (2000). DATE CONSIDERED **EXAMINER** 



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Sheet \_6\_ of \_6 Atty. Docket No. Serial No. **U.S. Department of Commerce** FORM PTO-1449 10/625,420 6960.US.P1 Patent and Trademark Office (Rev. 2032) INFORMATION DISCLOSURE Applicant STATEMENT BY APPLICANT Auestad, et al. Group Filing Date (Use several sheets if necessary) July 23, 2003 **U.S. PATENT DOCUMENTS** Class Subclass Filing Date (if appro.) Name Date Examiner **Document Number** Initial FOREIGN PATENT DOCUMENTS Translation (Yes No) Class Subclass Name Document Number OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Sugiura T, Kodaka T, Nakane S, Kishimoto A, Konda S, and Waku K. 2-Arachidonylglycerol: a possible endogenous cannabinoid ligand in brain. Biochem. Biophys. Res. Commun, 215:89-97, (1995). Sugiura T and Waku K. 2-Arachidonylglycerol: a possible multifunctional lipid mediator in the nervous and immune systems. Annals New York Academy of Sciences, VOL: 344-346, (2000). Van Dijk G, Chavez M, Reidy CA, and Woods SC. Adiposity signals and macronutrient selection. In: Neural and Metabolic Control of Macronutrient Intake. (H-R Berthoud and RJ Seeley, Eds). CRC Press, Boca Raton, FL. Chapter 30: 465-472, (2000). Wang Y, Liu Y, Ito Y, Hashiguchi T, Kitajima I, Yamakuchi M, Shimizu H, Matsuo S, Imaizumi H, and Maruyama I. Simultaneous measurement of anandamide and 2arachidonoylglycerol by polymyxin B-selective adsorption and subsequent high performance liquid chromatography analysis: increase in endogenous cannabinoids in the sera of patients with endotoxic shock. Analytical Biochemistry, 294:73-82, (2001). Ward GR, Huang YS, Bobik E, Xing H-C, Mutsaers L, Auestad N, Montalto M, and Wainwright P. Long-chain polyunsaturated fatty acid levels in formulae influence deposition of docosahexaenoic acid and arachidonic acid in brain and red blood cells of artificially reared neonatal rats. Journal of Nutrition, 128: 2473-2487, (1998). Ward GR, Huang Y-S, Xing H-C, Bobik E, Wauben I, Auestad N, Montalto M, and Wainwright PE. Effects of y-linolenic acid and docosahexaenoic acid in formulae on brain fatty acid composition in artificially reared rats. Lipids, 34: 1057-1063, (1999). Wainwright PE, Xing H-C, Ward GR, Huang Y-S, Bobik E, Auestad N, and Montalto M. Water maze performance is unaffected in artificially reared rats fed diets supplemented with arachidonic acid and docosahexaenoic acid. Journal of Nutrition, 129: 1079-1089, (1999).Williams CM and Kirkham TC. Anandamide induces overeating: mediation by central cannabinoid (CB<sub>1</sub>) receptors. Psychopharmacology, 143:315-317, (1999) Williams G, Harrold JA, and Cutler DJ. The hypothalamus and the regulation of energy homeostasis: lifting the lid on a black box. Proceedings of the Nutritional Society, 59:385-396, (2000). DATE CONSIDERED **EXAMINER**